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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/389,537	09/02/99	WARREN	P DIVER1250-1
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EXAMINER

SLOBODYANSKY, E

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

7
01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/389,537

Applicant(s)
Warren et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 17 and 18 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 17 and 18 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3,4
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The instant application is a continuation of application 08/646,590, now US Patent 5,962,283.

The preliminary amendment filed concurrently with the specification canceling claims 1-16 and 19-21 has been entered in part because the specification has 18 claims.

Claims 17 and 18 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is drawn to an enzyme having 70% identity to SEQ ID NOs 25-32.

While enzymes having amino acid sequences of SEQ ID NOs: 25-32 are aminotransferases and transaminases, it is unknown what enzyme, if any, will have an amino acid sequence that is 70% identical to said sequences. Therefore, claim 1 is directed to a vast diverse general class of proteins that are called enzymes. The specification does not disclose identifying characteristics which would allow to distinguish a mere protein from any enzyme or specifically an aminotransferase or

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transaminase. Thus, an enzyme of unknown specificity, said enzyme having 70% identity to SEQ ID NOs 25-32 lack sufficient written description.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an aminotransferase having amino acid sequences as set forth in SEQ ID NOs: 25-32, does not reasonably provide enablement for an aminotransferase or any other enzyme having an amino acid sequence 70% identical to SEQ ID NOs: 25-32. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988).

They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Despite knowledge in the art to produce mutations in proteins and the isolation of DNA molecules, the specification fails to provide guidance as to where, and what type of (i.e., what amino acid to substitute into, add to and/or delete from the known

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sequence), changes in amino acid residues will result in retention of the specific or any enzymatic activity. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The state of the art does not allow the predictability of the properties based on the structure. The amino acid sequence of a protein determines its structural and functional properties and knowledge of which residues can be altered or removed, so that they retain 70% identity, and still result in a specific or any enzymatic activity is well outside the realm of routine experimentation. Since the state of the art does not allow the predictability of the properties based on the structure, it is unpredictable what will be the function of a protein with the amino acid sequence 70% identical to SEQ ID Nos:25-32. Therefore, one skilled in the art would require guidance as to how to make an enzyme of an unspecified function with the amino acid sequence that is 70% identical to SEQ ID Nos:25-32 in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

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Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 18 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 16 of prior U.S. Patent No. 5,814,473. This is a double patenting rejection.

Claim 17 are rejected under the judicially created doctrine of double patenting over claim 15 of U. S. Patent No. 5,814,473 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: an enzyme of SEQ ID NOs: 25-32.

Claims 17 and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/412,184. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: an enzyme having at least 70% identity to SEQ ID NOs:25-32.

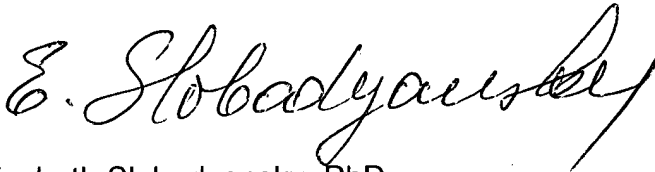
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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky".

Elizabeth Slobodyansky, PhD
Primary Examiner

January 26, 2001